DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-165/S-007, 008, and 009
NDA 21-300/S-001, 003, 004 and 005
NDA 21-312/S-006, 008, and 009

Schering Corporation
2000 Galloping Hill Road
Kenilworth, NJ 07033

Attention: Yvette Henderson
Manager, Global Labeling, Global Regulatory Affairs

Dear Ms. Henderson:

Please refer to your supplemental new drug applications dated November 11, 2004 (21-300/S-001), March 8, (21-165/S-007, 21-300/S-003 and 21-312/S-006), March 24, (21-165/S-008, 21-300/S-004, and 21-312/S-008), October 28, 2005 (21-165/S-009, 21-300/S-005, and 21-312/S-009) submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Clarinex® (desloratadine) Tablets, Syrup and RediTabs.

We acknowledge receipt of your submissions dated August 4, 2006 (NDA 21-165/S-009, 21-300/S-005 and NDA 21-312/S-009).

These "Changes Being Effected" supplemental new drug applications provide for the following labeling revisions.

21-300/S-001 – The addition of palpitations to the Observed During Clinical Practice subsection of the ADVERSE REACTIONS section.

21-165/S-007, 21-300/S-003 and 21-312/S-006 - The addition of "and very rarely hepatitis" to the Observed During Clinical Practice subsection of the ADVERSE REACTIONS section.

21-165/S-008, 21-300/S-004, and 21-312/S-008 - The addition of the following sentences to the Carcinogenesis, Mutagenesis, and Impairment of Fertility subsection of the PRECAUTIONS section.

> In a 2-year dietary study in mice, males and females given up to 16 mg/kg/day and 32 mg/kg/day of desloratadine, respectively, did not show significant increases in the incidence of any tumors. The estimated desloratadine and metabolite exposures of mice at these doses were 12 and 27 times, respectively, the AUC in humans at the recommended daily oral dose.

21-165/S-009, 21-300/S-005, and 21-312/S-009 – The addition of seizures and psychomotor hyperreactivity to the Observed During Clinical Practice subsection of the ADVERSE

REACTIONS section. The revision of the term hydroypropyl methylcellulose to hypromellose in the DESCRIPTION section and editorial revisions to the storage statement.

We completed our review of these applications, as amended. These applications are approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

The final printed labeling (FPL) must be identical to the submitted labeling (package insert submitted October 28, 2005).

Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no more than 30 days after it is printed. Individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, designate these submissions "**FPL for approved supplements NDA 21-165/S-007, 008, and 009, NDA 21-300/S-001, 003, 004 and 005 and NDA 21-312/S-006, 008, and 009**" Approval of these submissions by FDA is not required before the labeling is used.

If you issue a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH
Food and Drug Administration
WO 22, Room 4447
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Anthony M. Zeccola, Regulatory Management Officer, at (301) 796-1318.

Sincerely,

{See appended electronic signature page}

Badrul A. Chowdhury, M.D., Ph.D.
Director
Division of Pulmonary and Allergy Products
Center for Drug Evaluation and Research

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Badrul Chowdhury

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